52. (New) A method of detecting a lysosomal storage disorder (LSD), monitoring the progress of an LSD or the efficacy of treatment of an LSD in a human or animal subject, the method comprising assaying the level of an LSD marker in a biological sample derived from the subject, wherein the LSD marker is selected from the group consisting of Lamp-1, Lamp-2, Limp-II, mannose-6-phosphate receptors, α-L-iduronidase, 4-sulphatase, acid phosphatase (ACP), β-hexosaminidase, and α-mannosidase, or an immunologically interactive homologue, analogue or derivative thereof.

53. (New) The method according to claim 52, wherein the LSD marker is selected from the group consisting of Lamp-1, Lamp-2 and Limp-II, or an immunologically interactive homologue, analogue or derivative thereof.

54. (New) The method according to claim 53, wherein the LSD marker is selected from the group consisting of Lamp-1, Lamp-2 and Limp-II.

55. (New) The method according to claim 54, wherein the LSD marker is Lamp-1.

56. (New) The method according to claim 54, wherein the LSD marker is Lamp-2.

57. (New) The method according to claim 54, wherein the LSD marker is Limp-II.

58. (New) The method according to claim 52, wherein the biological sample comprises blood, plasma, urine, a fibroblast cell, a fibroblast cell culture or a fibroblast cellular extract.

59. (New) The method according to claim 54, wherein the biological sample comprises blood, plasma, urine, a fibroblast cell, a fibroblast cell culture or a fibroblast cellular extract.

60. (New) The method according to claim 59, wherein the biological sample comprises blood, plasma or urine.

61. (New) The method according to claim 59, wherein the fibroblast cell or fibroblast cell culture is a skin fibroblast or skin fibroblast cell culture or a cellular extract thereof.

62. (New) The method according to claim 61, wherein the fibroblast cell, fibroblast cell culture or fibroblast cellular extract is a Pompe, Salla, MPS II or MPS VI fibroblast cell, cell culture or cellular extract.

63. (New) The method according to claim 52, wherein the LSD is selected from the list set forth in Table 1.

64. (New) The method according to claim 63, wherein the LSD is selected from the group consisting of MPS I, MPS II, Gaucher disease, Pompe disease and Salla's disease.

65. (New) The method according to claim 52, wherein the step of assaying the level of an LSD marker comprises measuring the enzyme activity of said LSD marker in the biological sample.

66. (New) The method according to claim 52, wherein the step of assaying the level of an LSD marker comprises contacting the biological sample with one or more immunointeractive molecules specific for said LSD marker for a time and under conditions sufficient for the formulation of a complex to occur.

67. (New) The method according to claim 66, wherein the immunointeractive molecule is an antibody molecule that binds to the LSD marker.

68. (New) The method according to claim 67, wherein the antibody molecule is a monoclonal antibody that binds to the LSD marker.

69. (New) The method according to claim 66, wherein the immunointeractive molecule is labeled with a reporter molecule.

70. (New) The method according to claim 66, further comprising the step of contacting the complex formed between the LSD marker and the immunointeractive molecule with a labeled immunointeractive molecule for a time and under conditions sufficient for binding to occur.

71. (New) The method according to claim 70, wherein the labeled immunointeractive molecule is labeled with a reporter molecule.

72. (New) The method according to claim 69, wherein the reporter molecule is an enzyme, a fluorophore or a radionuclide molecule.

73. (New) The method according to claim 72, wherein the enzyme, fluorophore or radionuclide molecule is selected from the group consisting of horseradish peroxidase, glucose oxidase, β-galactosidase, alkaline phosphatase, fluorescein, Eu^{3+} and other lanthanide metals, and rhodamine.

74. (New) The method according to claim 52, wherein:

(a) the LSD is selected from the list set forth in Table 1;

(b) the LSD marker is selected from the group consisting of LAMP-1, LAMP-2, and LIMP-II;

(c) the biological sample comprises blood, serum or urine; and

(d) the assay comprises measuring the enzymatic activity of the LSD or is an immunoassay.

75. (New) A method of detecting a lysosomal storage disorder (LSD), monitoring the progress of an LSD or the efficacy of treatment of an LSD in a human or animal subject, the method comprising assaying the level of an LSD marker in a biological sample obtained from the subject, wherein the LSD marker is an enzyme, a polypeptide or a protein which is associated with the occurrence, development or onset of the LSD, and the level of the LSD marker in the subject is elevated relative to the level of the LSD marker for a control.

76. (New) The method of claim 75, wherein the levels of the LSD marker in the subject and control are concentration values.

77. (New) The method of claim 75, wherein the levels of the LSD marker in the subject and control are rates of accumulation.

78. (New) The method according to claim 75, wherein the level of the LSD marker in the subject is at least 2-fold higher than the level in the control.

79. (New) The method according to claim 78, wherein the level of the LSD marker in the subject is at least 5-fold higher than the level in the control.

80. (New) The method according to claim 79, wherein the level of the LSD marker in the subject is at least 10-fold higher than the level in the control.

81. (New) The method according to claim 80, wherein the level of the LSD marker is at least 20-fold higher than the level in the control.

82. (New) The method according to claim 75, wherein the control is an individual unaffected by an LSD.

83. (New) The method according to claim 75, wherein the control is a population of individuals unaffected by an LSD.

84. (New) The method according to claim 75, wherein the elevated LSD marker is selected from the group consisting of Lamp-1, Lamp-2, Limp-II, mannose-6-phosphate receptor, α-L-iduronidase, 4-sulphatase, acid phosphatase (ACP), β-hexosaminidase, and α-mannosidase, or an immunologically interactive homologue, analogue or derivative thereof.

85. (New) The method according to claim 84, wherein the elevated LSD marker is selected from the group consisting of Lamp-1, Lamp-2 and Limp-II, or an immunologically interactive homologue, analogue or derivative thereof.

86. (New) The method according to claim 85, wherein the elevated LSD marker is selected from the group consisting of Lamp-1, Lamp-2 and Limp-II.

87. (New) The method according to claim 86, wherein the elevated LSD marker is Lamp-1.

88. (New) The method according to claim 86, wherein the elevated LSD marker is Lamp-2.

89. (New) The method according to claim 86, wherein the elevated LSD marker is Limp-II.

90. (New) The method according to claim 86, wherein the biological sample comprises blood, plasma, urine, a fibroblast cell, a fibroblast cell culture or a fibroblast cellular extract.

91. (New) The method according to claim 90, wherein the biological sample comprises blood, plasma or urine.

92. (New) The method according to claim 86, wherein the subject is asymptomatic for a LSD.

93. (New) A method for detecting a lysosomal storage disorder (LSD), comprising assaying LAMP-1, LAMP-2 or LIMP-II in a sample of blood obtained from a patient that is asymptomatic for a LSD.

94. (New) The method according to claim 93, further comprising determining whether the level of LAMP-1, LAMP-2 or LIMP-II in the patient is elevated relative to the corresponding level of LAMP-1, LAMP-2 or LIMP-II in a control.

REMARKS

Claims 1-10, 12, 16, 17, 19 and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Michaelakakis *et al.* as evidenced by Aerts *et al.*

Claims 11, 13-15, 18 are objected to by the Examiner. In a phone conversation with the Examiner on May 23, 2000, the Examiner stated that these claims stand rejected only as depending upon a rejected independent claim and that these claims would be allowable if rewritten in independent form including all of the elements of the base claim and any intervening claims.

Initially, it is questioned whether the rejection can properly be brought under Section 102 given that the Examiner relies on combining two references. Multiple references can be cited in making a Section 102 rejection in only limited circumstances (MPEP 2131.01),